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07/24/2006

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



## **DETAILED ACTION**

### ***Claim Objections***

Claim 4 is objected to because of the following informalities: Claim 4 recites sodium acetate as one of the Markush members for polar solvents. Sodium acetate is a salt and not a solvent. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the separation of glycolipids using a combination of chloroform, methanol, water and pyridine as solvents, does not reasonably provide enablement for the same for any and all other solvent combinations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The level of one of ordinary skill

Art Unit: 1623

- (C) The amount of direction provided by the inventor
- (D) The existence of working examples
- (E) The level of predictability in the art
- (F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**The breadth of the claims**

Instant claim 1 is drawn to a method of separating glycolipids comprising contacting a sample solution via a semipermeable membrane with a solution having a lower osmotic pressure till the sample solution separates into two or three layers and separating the middle and/or bottom layer. The sample solution and the solution of lower osmotic pressure as instantly recited are broad and are seen to include any solvent or combination of solvents.

**The level of one of ordinary skill in the art**

The level of skill of those in this art is that of one having experience in organic synthesis/separation.

**The amount of direction provided by the inventor**

The instant specification is not seen to provide adequate guidance, which would allow the skilled artisan to extrapolate from the disclosure and examples provided, to use the claimed method commensurate in scope with the instant claims. There is a lack of data and examples that adequately represent the claims as written.

**The existence of working examples**

The working examples set forth in the instant specification are drawn to extraction of glycolipids from mice via dialysis of a sample solution wherein the sample solution comprises a combination of chloroform/aqueous methanol and pyridine and wherein the solution of lower osmotic pressure is distilled water. The sample solution already has three immiscible solvents to

Art Unit: 1623

begin with. One of ordinary skill in the art will not extrapolate this to a combination of any other solvent since the examples provided are not representative of any other solvent combinations encompassed by the broad recitation of instant claim 1.

**The level of Predictability in the Art**

Partitioning of samples can be partial or total and depends on the solvents used and the nature of the sample and its solubility differences in solvents used. Just because a sample is highly soluble in one solvent does not mean it will be soluble to the same extent in another similar solvent.

**The quantity of experimentation needed to make or use the invention based on the content of the disclosure**

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to represent any or all solvent combinations encompassed by the recitation of the instant claims. One of ordinary skill in the art would have to carry out undue experimentation to practice the instant invention. One of ordinary skill in the art would be required to perform undue experimentation to determine which, if any, of the several solvent combinations would be useful to separate the glycolipids recited in instant claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1623

Claim 1 recites hydrolysis of an extract derived from a biological sample with a mixture of polar and non-polar solvents. It is not clear how using a solvent alone performs hydrolysis. The claim recitation is unclear as to what applicants mean.

### ***Conclusion***

Claims 1-6 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

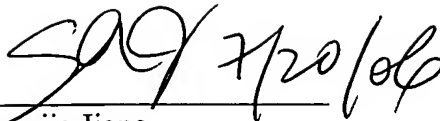
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Application/Control Number: 10/825,210

Page 6

Art Unit: 1623

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Art Unit 1623